ISRCTN13472393 https://doi.org/10.1186/ISRCTN13472393

Isometric exercise for people with raised blood pressure

Submission date 07/09/2020	**Recruitment status** No longer recruiting	[X] Prospectively registered [X] Protocol [X] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 18/09/2020	**Overall study status** Completed	
Last Edited 09/06/2025	**Condition category** Circulatory System	

Plain English summary of protocol

Current plain English summary as of 07/01/2022:
Background and study aims
High blood pressure affects many people in the UK. People with raised blood pressure (140-159 /90-99 mmHg) are recommended to make changes in their lifestyle (e.g. smoking/alcohol/diet /exercise) and/or medication in order to reduce their blood pressure. Current knowledge suggests that a particular type of exercise - isometric exercise - can lower blood pressure. Isometric exercise involves holding a fixed body position for a short period of time. As most of the information about the benefits of this type of exercise comes from laboratory-based studies, researchers want to find out if it is possible for NHS healthcare professionals to offer NHS patients with clinically high blood pressure an isometric exercise plan to do at home and how it might affect their blood pressure over 6 months. They will also find out the experiences of those doing this type of exercise and whether it can be done consistently at home over time.

Who can participate?
Adults over the age of 18 with high blood pressure (systolic blood pressure of 140-159 mmHg)

What does the study involve?
Participants will be identified as potentially eligible by their GP surgery or through their secondary care healthcare professional. They will then be invited to take part in the study either at their local GP surgery or another local secondary care research site. Upon consent, they will be asked to complete 5 days of home blood pressure monitoring followed by a screening appointment, involving checks of medical history and medication. They will also be asked to complete an isometric exercise ability test involving a 60-second wall squat to determine if they will be able to do the basic exercise. Once this is completed, participants will be randomly allocated to one of two groups. Those in the first group will be given standard care/lifestyle advice for raised blood pressure and asked to record their blood pressure for five days at weeks 4, 12 and 24. The second group will also be given standard care/lifestyle advice and prescribed an individualised isometric exercise programme. In order to prescribe this, the participant will be asked to visit their local research site to undertake a short isometric exercise test. They will then be asked to complete the isometric exercise training thrice weekly for 6 months, along with the blood pressure measurements at weeks 4, 12 and 24. Participants will also be asked to complete questionnaires at week 4, week 12 and week 24.

What are the possible benefits and risks of participating?
Participants in the isometric exercise group may benefit from improvements in leg strength and fitness over the training period which could benefit long-term health. They may also experience a reduction in blood pressure. After 6 months the control participants will also get an opportunity to complete the isometric exercise training.
Participants may take a while to get used to doing the exercise and may initially feel unbalanced whilst doing the isometric wall squats. Participants may experience a burning sensation in their legs as well as their body temperature increasing and heart beating faster. This is the body's normal reaction to performing the exercise and should lessen as participants get used to the exercise plan. Following the exercise sessions, participants may experience slight muscle aching in the following 48-hour period during the early points of the exercise training plan. This would be a perfectly normal response to the exercise and should have no long-lasting effects. Blood pressure and heart rate increase during isometric exercise, but there is currently no evidence to suggest that this presents any risk to individuals with already elevated blood pressure. The risks of sudden heart problems (like a heart attack) during or after doing isometric exercise are very low. Participants will receive a phone call after the first week of exercise to check they are happy with their exercise plan and to collect heart rate and blood pressure data from the first week to check they are exercising at the right level of difficulty. Participants will be asked to inform the researchers straight away if they experience any problems whilst participating in the study. If the study team are concerned about a participant's safety from the information collected throughout the study their GP will be informed. Provisions have been made for reducing the risk of contracting COVID-19. These include minimising the number of visits to a research clinic (either 0 or 1) and if/when participants have to visit, the necessary personal protective equipment will be worn by the research staff with any social distancing procedures in place at the site being followed.

Where is the study run from?
Canterbury Christ Church University (UK)

When is the study starting and how long is it expected to run for?
April 2019 to June 2023

Who is funding the study?
National Institute for Health Research (NIHR) (UK)

Who is the main contact?
Dr Jonathan Wiles
Jim.wiles@canterbury.ac.uk

Previous plain English summary:
Background and study aims
High blood pressure affects many people in the UK. People with raised blood pressure (140-159 /90-99 mmHg) are recommended to make changes in their lifestyle (e.g. smoking/alcohol/diet /exercise) and/or medication in order to reduce their blood pressure. Current knowledge suggests that a particular type of exercise - isometric exercise - can lower blood pressure. Isometric exercise involves holding a fixed body position for a short period of time. As most of the information about the benefits of this type of exercise comes from laboratory-based studies, researchers want to find out if it is possible for GP practices to offer NHS patients with clinically high blood pressure an isometric exercise plan to do at home and how it might affect their blood pressure over 6 months. They will also find out the experiences of those doing this type of exercise and whether it can be done consistently at home over time.

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Study website
https://www.canterbury.ac.uk/science-engineering-and-social-sciences/psychology-and-life-sciences/sport-and-exercise-sciences/research/isometric-research-group/Isofit-bp-study.aspx

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

274676

ClinicalTrials.gov number
NCT04936022

Secondary identifying numbers
IRAS 274676, CPMS 45195

Study information

Scientific Title
Feasibility study to assess the delivery of a novel isometric exercise intervention for people with Stage 1 hypertension in the NHS

Acronym
IsoFIT-BP

Study objectives
Current study hypothesis as of 07/01/2022:
Isometric exercise can be successfully delivered to patients with Stage 1 hypertension in an NHS setting.

Previous study hypothesis:
Isometric exercise can be successfully delivered to patients with Stage 1 hypertension in an NHS primary care setting.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 22/05/2020, London - Bromley Research Ethics Committee (Level 3, Block B, Whitefriars, Lewins Mead, Bristol, BS1 2NT, UK; +44 (0)207 104 8105, +44 (0)207 104 8063; bromley.rec@hra.nhs.uk), REC ref: 20/LO/0422

Study design
Multi-centre randomized controlled feasibility study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

Available on study website

Health condition(s) or problem(s) studied
Stage 1 hypertensive patients (defined as a clinic BP of 140-159/90-99 mmHg) who are not taking anti-hypertension medication

Interventions
Participants will be randomized into two groups, the intervention arm and the control arm, in a 1:1 ratio using sealed envelope software. Both groups will receive standard care/lifestyle advice and have their blood pressure monitored at week 1, week 12 and week 24. In addition, the intervention arm will be prescribed 6 months of isometric exercise training (three sessions per week, comprised of 4 x 2-minute bouts with 2-minute recovery periods in-between). The isometric exercise group will also be asked to complete a questionnaire about their experience of the exercise training, at week 4 and there will be a focus group asking the participants about their experience of the training, at month 4 and month 8.

Intervention Type
Behavioural

Primary outcome measure
Current primary outcome measure as of 07/01/2022:
1. Feasibility of isometric exercise prescription assessed using qualitative data from healthcare professional focus groups at month 11/12 of the study
2. Variance of blood pressure changes from baseline using participant blood pressure data at week 4, months 3 and 6
3. Sample size for a definitive randomised controlled trial, calculated using evidence of effect on participant systolic blood pressure change at week 1, months 3 and 6

Previous primary outcome measure:
1. Feasibility of isometric exercise prescription assessed using qualitative data from healthcare professional focus groups at month 11/12 of the study
2. Feasibility of isometric exercise intervention and study assessed using qualitative data from participants at month 7 and 11 of the study
3. Variance of blood pressure changes from baseline using participant blood pressure data at week 4, months 3 and 6
4. Sample size for a definitive randomised controlled trial, calculated using evidence of effect on participant systolic blood pressure change at week 1, months 3 and 6

Secondary outcome measures
Current secondary outcome measures as of 07/01/2022:
1. Fidelity of the isometric exercise prescription measured using prescription competency assessment data at month 3
2. Fidelity of the isometric exercise prescription measured using observation data from the first Incremental Isometric Exercise Test (IIET) delivered from month 3 to month 5
3. Fidelity of the isometric exercise prescription defined by participant heart rate data within HR reference intervals at Day 7-10
4. Short and medium-term adherence rates recorded as those adhering to isometric exercise intervention at week 4, month 3 and month 6
5. Recruitment and attrition rates from data collected at sites at month 10 and month 15
6. GPs and healthcare professionals' attitudes to isometric exercise as a treatment option for patients, measured using remote focus groups and telephone interviews at month 11/12

7. Cost and cost-utility of the isometric exercise intervention using healthcare resource use data and quality-adjusted life years (QALYs) at month 15 (or last patient follow up)
8. Participant experiences of undertaking isometric exercise using participant isometric exercise experience surveys at week 4
9. Feasibility of isometric exercise intervention and study assessed using qualitative data from participants at month 7 and 11 of the study
10. Effect of COVID-19 on recruitment rates and participation using participant focus groups or telephone calls at month 7 and 11 of the study
11. Feasibility of using observed home blood pressure readings for remote blood pressure monitoring, using participant blood pressure data and observations from the measures at day 1, week 4, month 3 and month 6

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1. Fidelity of the isometric exercise prescription measured using prescription competency assessment data at month 3
2. Fidelity of the isometric exercise prescription measured using observation data from the first Incremental Isometric Exercise Test (IIET) delivered from month 3 to month 5
3. Fidelity of the isometric exercise prescription defined by participant heart rate data within HR reference intervals at Day 7-10
4. Short and medium-term adherence rates recorded as those adhering to isometric exercise intervention at week 4, month 3 and month 6
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6. GPs and healthcare professionals' attitudes to isometric exercise as a treatment option for patients, measured using remote focus groups and telephone interviews at month 11/12
7. Cost and cost-utility of the isometric exercise intervention using healthcare resource use data and quality-adjusted life years (QALYs) at month 15 (or last patient follow up)
8. Participant experiences of undertaking isometric exercise using participant isometric exercise experience surveys at week 4
9. Effect of COVID-19 on recruitment rates and participation using participant focus groups or telephone calls at month 7 and 11 of the study
10. Feasibility of using observed home blood pressure readings for remote blood pressure monitoring, using participant blood pressure data and observations from the measures at day 1, week 4, month 3 and month 6

Overall study start date
01/04/2019

Completion date
30/06/2023

Eligibility

Key inclusion criteria
1. Aged 18 or over
2. Clinic systolic BP 140-159 mmHg
3. Able to provide informed consent

Participant type(s)
Patient

Age group

Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
100

Total final enrolment
84

Key exclusion criteria
1. Currently taking anti-hypertensive medication
2. White coat hypertension, as evidenced by averaged home systolic BP <135 mmHg
3. Inability to undertake study intervention (isometric exercise)
4. Previous history of any of the following:
4.1. Diabetes mellitus (Type 1 or type 2)
4.2. Ischaemic heart disease (myocardial infarction and/or coronary angina and/or coronary revascularization procedure)
4.3. Moderate or severe stenotic or regurgitant heart valve disease
4.4. Atrial or ventricular arrhythmia
4.5. Stroke or transient ischaemic attack
4.6. Aortic aneurysm and/or peripheral arterial disease
4.7. Uncorrected congenital or inherited heart condition
5. Estimated glomerular filtration rate <45 ml/min (calculated using CKD-EPI or MDRD formulae, and taking most recent documented results)
6. Documented left ventricular ejection fraction <45% and/or left ventricular hypertrophy (by either echocardiography or standard ECG criteria e.g. Sokolow-Lyon)
7. Documented urine albumin:creatinine ratio >3.5 mg/mmol
8. Inability to provide informed consent
9. If female, pregnancy or currently breastfeeding
10. Enrolled in another Clinical Trial of an Interventional Medicinal Product or Medical Device or another interventional study
11. Medical condition that, in the opinion of the investigator, would make the participant unsuitable for the study

Date of first enrolment
18/01/2021

Date of final enrolment
31/03/2022

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Newton Place Surgery
Newton Road
Faversham
United Kingdom
ME13 8FH

Study participating centre
Northgate Medical Practice
1, Northgate
Canterbury
United Kingdom
CT1 1WL

Study participating centre
Canterbury Medical Practice
Patrixbourne Road
Bridge
Canterbury
United Kingdom
CT4 5BL

Study participating centre
Kent & Canterbury Hospital
Ethelbert Road
Canterbury
United Kingdom
CT1 3NG

Study participating centre
Maywood Healthcare Centre
225 Hawthorn Road
Bognor Regis
United Kingdom
PO21 2UW

Sponsor information

Organisation
East Kent Hospitals University NHS Foundation Trust

Sponsor details
Kennington Road
Willesborough
Ashford
England
United Kingdom
TN24 0LZ
+44 (0)1233 633331
caroline.cowley@nhs.net

Sponsor type
Hospital/treatment centre

Website
http://www.ekhuft.nhs.uk/patients-and-visitors/

ROR
https://ror.org/02dqqj223

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan

This research will lead to the following outputs: published guidelines for training and delivery of a home-based IE intervention for Stage 1 hypertensive patients in the NHS; data to inform sample size estimates for a substantive trial; a patented IE tool and copyrighted training manual for the IE intervention delivery; the identification of barriers and enablers for delivering this intervention in the NHS; and a funding application and protocol for a substantive randomised controlled trial in the NHS to establish effectiveness and mechanisms of IE action in reducing BP in this population.

The results of the study will be disseminated through local, national and social media. The researchers will present their results at national and international conferences (e.g. UKactive Summit) and publish findings in high-impact, open-access peer-reviewed journals in the field where the project team's previous work has been well-received (e.g. Hypertension, Journal of Human Hypertension, Journal of Hypertension, Journal of Applied Physiology, PLOS Medicine, British Medical Journal).

Study participants will receive a personalised report of their own results and a summary of study findings will also be sent to GP practices and local organisations (E.g. CCCCG, EKHUFT, Kent and Medway STP, Kent AHSN and NIHR CRN:KSS). The study final report will be submitted and a lay summary disseminated to a wider audience to create national impact by engaging with policy and national governing body organisations (e.g., PHE, NICE, National Centre for Sport & Exercise Medicine), third sector organisations (e.g. BHF, BHS) with the aim of understanding the evidence required to influence current hypertension treatment guidelines with respect to offering lifestyle interventions like IE as standard care and a tangible product that can be marketed in the NHS.

Intention to publish date

31/08/2023

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are/will be available upon request from Dr Jonathan Wiles (jim.wiles@canterbury.ac.uk). The data will become available 1 year after the study finishes which will be approximately December 2022 and may be accessed for up to 5 years. Anonymised data may be accessed by researchers at universities, NHS organisations or other healthcare providers where the sharing of data has a clearly defined purpose and its use will be of benefit to wider society. Data will be shared by secure data transfer. Consent from participants was obtained for the use of their information for future research and to be shared anonymously with other researchers.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file	version V3.2.1	01/10/2020	10/11/2020	No	No
Protocol (preprint)		19/01/2021	29/07/2021	No	No
Protocol article		28/10/2021	01/11/2021	Yes	No
Protocol file	version 4	30/09/2021	07/01/2022	No	No

Other publications	critical discussion of study feasibility and adaptations during the COVID-19 pandemic	17/03/2023	24/03/2023	Yes	No
Statistical Analysis Plan	version 1.2		08/06/2023	No	No
HRA research summary			28/06/2023	No	No
Results article	Secondary outcome: embedded qualitative study on participant and stakeholder perceptions	26/08/2024	29/08/2024	Yes	No
Results article	Feasibility	04/06/2025	09/06/2025	Yes	No